

Claim 4 was amended to clarify the propagating step as described in further detail below. Claim 38 was added as a result of amendments made to claim 4.

Claim 7 has been amended by deleting the comma as suggested by the Examiner.

Claim 10 has been amended to incorporate claim 12.

Amendments to claim 19 were made to put the claim in proper multiple dependent form.

No new matter has been introduced by the claim amendments. Applicants respectfully request entry and consideration of the amendments.

Priority

As suggested by the Examiner, the first sentence of the instant specification has been amended to claim priority to Provisional Application No. 60/088,321, filed on August 5, 1998 and Provisional Application No. 60/081,867, filed on April 15, 1998, where the instant application is a 35 U.S.C. §371 filing of PCT/US99/08294 filed April 15, 1999.

Response to Claim Rejections Under 35 USC §101

Applicants acknowledge withdrawal of the rejection to claims 21-37 under 35 U.S.C. §101.

Response to Claim Rejections Under 35 U.S.C. §112, First Paragraph

Applicants respectfully acknowledge withdrawal of the rejection to claims 1-19 under 35 USC §112, First Paragraph.

Response to Claim Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 4 and 7 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner contends that while the "propagating step in claim 1 (from which claim 4 depends) requires propagating a DNA delivery adenoviral vector and helper adenoviral vector...claim 4 only recites propagating the

helper adenoviral vector" (Office Action dated 5/19/03, pg. 4). Applicants respectfully disagree with the Examiner's contention. The method of claim 4 simply describes the propagating step for the helper adenovirus and the repressing step in more detail, independent of the propagating step for the DNA delivery vector. As it is well understood, the phrase "according to claim 1" indicates that in addition to the steps of claim 1, claim 4 adds additional features. However, in order to expedite prosecution of the instant application, applicants have amended claim 4 in order to address the Examiner's concerns. For clarification, claim 1 has been amended to separate the propagating steps for the helper adenovirus vector and the DNA delivery adenovirus vector. Additionally, claim 38 has been added as a result of amendments to claim 4. Therefore, applicants respectfully request withdrawal of this ground of rejection.

With respect to claim 7, the Examiner contends that the claim is indefinite for not defining whether the A repeat VI element is part of SEQ ID NO: 1 or a COUP-TF binding site. Applicants respectfully disagree, however in order to expedite prosecution of the instant application, applicants have amended the claim as suggested by the Examiner to remove the comma after the term "sites" on line 3 of the claim. Thus, reconsideration and withdrawal of the §112, second paragraph rejection is respectfully requested.

Response to Claim Rejections Under 35 U.S.C. §102

Claims 10, 11, 12, 15 stand rejected under 35 U.S.C. §102 as being anticipated by Schmid, et al. (J. Virol. 71:3375-3384, 1997) as evidenced by Schmid, et al. (J. Virol. 72:6339-6347, 1998). Schmid, et al. analyze the 21-bp region separating A repeats I and II and A repeats V and VI. The Examiner contends that Figure 1 of Schmid, et al. (1997) anticipates claim 10, 11, 12, and 15 of the instant application. As the Examiner points out, Schmid does not specifically teach that the packaging sequence contains the COUP-TF repressor binding site. The Examiner provides Schmid, et al. 1998 as evidence that a repressor binding site flanks the packaging signal sequence. However, Schmid, et al. report that the "AVI probe contains highly conserved dimeric consensus binding sites for a cellular transcription factor, COUP-TF...These binding sites overlap AVI (5'-GGACTTTGACC-3'); only the upper strand is indicated, with the

COUP-TF half sites underlined and AVI indicated in boldface" (Schmid, 1998; pg. 6343, para. bridging cols. 1 and 2).

Contrary to the Examiner's contention that "Schmid (1997) teaches that the adenovirus vector has a packaging sequence (AV or AVII) that is flanked by the repressor-binding site," one skilled in the art would understand that the COUP-TF binding site does not flank the packaging signal sequence, rather the A repeat VI element contains the COUP-TF binding site. Therefore, amended claim 10 which recites: "a packaging signal sequence consisting of at least two copies of 5'-TTTGN₈CG-3'(SEQ ID NO:1) and an A repeat VI element, wherein a repressor binding site flanks the packaging signal sequence" is not anticipated by Schmid, et al. Since applicants amended claim 10 by incorporating the subject matter of claim 12 where the repressor binding site flanks the packaging signal sequence, reconsideration and withdrawal of this §102 rejection is respectfully requested.

Claims 10, 11, 12, 15 stand rejected under 35 U.S.C. §102 as being anticipated by Schmid, et al. (*J. Virol.* 72:6339-6347, 1998). As previously discussed, applicants have amended claim 10 in order to expedite prosecution of the instant application. Reconsideration and withdrawal of this §102 rejection is respectfully requested.

Allowance of the pending claims is respectfully requested. Early and favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 3927-4133US2.

Respectfully submitted

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Dated: August 19, 2003

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